15 November 2012
EMA/CHMP/724928/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

TachoSil

Human fibrinogen/human thrombin

On 15 November 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product TachoSil. The marketing authorisation holder for this medicinal product is Nycomed Austria GmbH. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new contraindication as follows:

"TachoSil must not be applied intravascularly."

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full contraindications for Tachosil will be as follows[2]:

"**TachoSil must not be applied intravascularly.**"
Hypersensitivity to the active substances or to any of the excipients listed in section 6.1".

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] The text in bold represents the new or the amended contraindication.

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